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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,041	12/01/2003	Jamieson Crawford	3896-031547 (P-6059)	2967

32182 7590 03/09/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL  
BECTON DICKINSON AND COMPANY  
[THE WEBB LAW FIRM]  
FRANKLIN LAKES, NJ 07414-1880

EXAMINER
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WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/725,041	Applicant(s) CRAWFORD, JAMIESON	
	Examiner Catherine N. Witczak	Art Unit 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

The indicated allowability of claims 10 and 11 is withdrawn in view of the newly discovered reference(s) to Jansen et al (US 2002/0004649). Rejections based on the newly cited reference(s) follow.


#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US 6,659,983) in view of Jansen et al (2002/0004649).

Claims 1 and 11: Crawford et al disclose in Figure 1 a hub having opposed proximal and distal end and a passage extending therebetween (14); an elongated shield housing having a first open end and an opposed second open end with a passageway in between (20); a needle cannula having a distal puncture tip (16) which extends from the hub housing with at least a portion of the needle cannula extending through the passageway of the shield housing; a biasing member acting on the shield housing to bias the shield toward a second position covering the distal puncture tip of the needle cannula (22); and an engagement mechanism (12) in releasable engagement with the shield housing (50) which maintains the shield housing in the first biased position adjacent the hub housing and when engaged, releases the shield housing allowing it to move toward the second position.

  
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Crawford et al disclose the claimed invention except for the hub housing comprising a flexible, inwardly biased cut out portion adapted for engagement with a portion of the shield housing. Jansen et al teach that it is known to use a hub housing (26) comprising a flexible, inwardly biased cut out portion (52) adapted for engagement (58) with a portion of the shield housing (28) as set forth in Figure 4 to prevent retraction of the shield once extended (paragraph 0027). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Crawford et al with a hub housing comprising a flexible, inwardly biased cut out portion adapted for engagement with a portion of the shield housing, since such a modification would prevent retraction of the shield once retracted.

Claim 2: Crawford et al disclose in Figure 1 a first member extending dorsally from the hub housing (40), a second member extending from a portion of the first member (44), with the second member moveable with respect to the first member so as to release from engagement with the shield housing (column 3, lines 22-26).

Claim 3: Crawford et al disclose in Figure 1 a latch element extending dorsally from the shield housing (50) including a recess or opening (52) for engagement with the engagement mechanism of the hub housing.

Claim 4: Crawford et al disclose in Figure 1 the second member of the engagement mechanism (44) having a hook element (48) for engagement with the recess of the latch element.

Claim 5: Crawford et al disclose in Figure 1 the second member of the engagement mechanism (44) connected to the first member of the release mechanism (40). Furthermore, Crawford et al disclose in

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column 3 lines 7-8 that the connection between the two allows for resilient deflection of the second member, wherein this description reads on the connection of the first (40) and second (44) members being a fulcrum.

Claim 6: Crawford et al disclose in Figure 1 first (40) and second (44) member of the engagement mechanism including corresponding surfaces for movement toward each other about the fulcrum, and further disclose in column 3, lines 21-26 that this releases the hook element from the recess/opening of the latch element.

Claim 7: Crawford et al disclose in column 2, lines 6-11 that the hub housing comprises structure for attachment to a medical device.

Claim 8: Crawford et al disclose in column 3, lines 15-17 the use of a compression spring as a biasing member.

Claim 12: Crawford et al disclose in Figure 1 a set of wings extending from opposing lateral sides of hub housing (66). Furthermore, in column 1, lines 14-16, Crawford et al disclose that these wings are flexible.

Claim 13: Crawford et al disclose in Figure 1 the engagement mechanism (40) extending dorsally from the hub housing (14) bisecting the flexible wings (66). Furthermore, Crawford et al disclose in column 3, lines 20-22 a method of activation of the engagement mechanism which would not be possible to achieve simply by bending the flexible wings toward a dorsal position.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine Witczak  
Junior Examiner  
Art Unit 3767



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**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**